

EV 336512225 US 07/14/2003

Application Number

First Named Inventor

Filing Date

AP 1653

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Paul Weigel, e Group Art Unit Examiner Name

09/469 200

12/21/1999

1653 /FCH 18 2003 G. Bugaisky ENTER 1600/290 Total Number of Pages in This Submission Attorney Docket Number **ENCLOSURES** (check all that apply) After Allowance Communication Assignment Papers (for an Application) X Fee Transmittal Form to Group Appeal Communication to Board Fee Attached Drawing(s) of Appeals and Interferences Licensing-related Papers Appeal Communication to Group Amendment / Reply (Appeal Notice, Brief, Reply Brief) After Final Proprietary Information Petition to Convert to a Provisional Application Affidavits/declaration(s) Status Letter Power of Attorney, Revocation Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request identify below): Terminal Disclaimer See remarks below: Express Abandonment Request Request for Refund \mathbf{x} Information Disclosure Statement CD. Number of CD(s)_ Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Transmittal Form (1 pege); 1. International Control (page);
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A information Dublouse Statement () pag Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm DUNLAP, CODDING & ROGERS, P.C., Customer Number 30589 Douglas J. Sorocco, P. O. Box 16370, Oklahoma City, Oklahoma 73113 Individual name Signature Date 7.19.2003

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PROBLEMS ASSESSED FRANCE. 36.6 (alb) 1 114-17 (67

PTO/SB/17 (10-02)
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Applicant claims small entity status. See 37 CFR 1.27

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Name (PrinuType) Quiglas Sorocco	5	egistra Ntomev/	tion No.	43	,145	Telephone	(405) 607-86	300
Signature		morrey.	ngurii)			Date	07/14/2003	

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Sheet 1

PTO/SB/08 (08-00)
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)

of 5

TECHCENTER GOOZOO C mplete if Known Application Number 09/469.200 12/21/1999 Filing Date First Named Inventor Paul Weigel, et al. Group Art Unit 1653 G. Bugaisky Examiner Name 35541.011 Attorney Docket Number

HE DATENT DOCUMENTS

				U.S. PATENT DOCU	MENIS		۲v
Examiner Initials*	Cite No.1		ment d Code ² known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	1	RE37336	T	Weigel, et al.	08/21/2001		\neg
	2	4224179	Т	Schneider	09/23/1980		
	3	4235871	T	Papahedjopoulos, et al.	11/25/1980		
	4	4511478		Nowinski, et al.	04/16/1985		
	5	4517295		Brecke, et al.	05/14/1985		
	6	4615697	Γ	Robinson	10/07/1966		
	7	4708861		Popescu, et al.	11/24/1987		
	в	4780414		Nimrod, et al.	10/25/1988		
	9	4782046		Brown, et al.	11/01/1988		
	10	4784990		Nimrod, et al.	11/15/1988		
	11	4801539	1	Akasaka, et al.	01/31/1989		
	12	4822867		Erhan	04/18/1989		_
	13	4983392		Robinson	01/08/1991		
	14	5015577		Weigel, et al.	05/14/1991		
	15	5023175		Hosoye, et el.	06/11/1991		_]
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	17	5171689	T	Kawaguri, et al.	12/15/1992		
	18	5217743		Farah	06/08/1993		_
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	20	5472704	1	Santus, et al.	12/05/1995		•

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Examiner Initials	Cite No.1	Office	Foreign Patent Do Number4	Kind	Codes	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Pesseges or Relevant Figures Appear	To
	Α		0036776 EPO			Kleid, et al.	05/11/1988		Τ
	В		0144019 EPO			Brown, et al.	06/13/1990		T
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	D		0244757 EPO			Hospya, et al.	11/09/1994		
	E		0266578 EPO			Miyamori, et al.	07/07/1993		
	F		91/03559 WO			Weigel, et al.	03/21/1991		Ι_
	G		94/00463 WO		_	Prehm, et al.	01/06/1994		
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	ī		95/33067 WO			Stohl, Sten	12/07/1995		
	J		97/20061 WO			Wong, et al.	06/05/1997		

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WPO Standard S13, ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbious as indicated on the document number WIPO Standard S1. ⁷ Isl in the patent document. ⁵ Kind of document by the appropriate symbious as indicated on the document number WIPO Standard S1. ⁷ Isl in the patent document. ⁵ Kind of document by the appropriate symbious as indicated on the document number with the patent document. ⁵ Kind of document by the appropriate symbious indicated on the document. ⁵ Islandard S1. ⁵ Isl possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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OF USE OF Complete if Known Application Number Filing Date First Named Inventor Group Art Unit

STATEMENT BY APPLICANT (use as many sheets as necessary)

Examiner Name Attorney Docket Number Sheet 2 of 5

T			1	U.S. PATENT DOCU	JMENTS	
Examiner Initials	Cite No.1	U.S. Patent Number	Document Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	21	5473034		Yasui, et al.	12/05/1995	
	22	5607694		Marx	03/04/1997	
	23	5610241		Leo, et al.	03/11/1997	
	24	5622850		Sloma, et al.	04/22/1997	
	25	5631019		Marx	05/20/1997	
	26	5651982		Marx	07/29/1997	
	27	5948900		Yother, et al.	09/07/1989	
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	К		8-38336 JP		Itano, et al.	1998		
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¹ Unique citation designation number, 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Sheet 3

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		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	_
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, sympostum, catalog, etc.), date, nage(s), volume-issue number(s), publisher, city and/or country where published.	T2
	AA	"THE PRODUCTION OF CAPSULES, HYALURONIC ACID AND HYALURONIDASE BY GROUP A AND GROUP C STREPTOCOCCI", MacLennan, J. Gen. Microbiol., 14:134-142 (1956).	
	вв	'THE ISOLATION AND CHARACTERIZATION OF A HYALURONIDASE PRODUCED BY A CAPSULATED STRAIN OF GROUP C STREPTOCOCCUS', MacLennan, J. Gen. Microbiol., 14:143-152 (1956).	
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	DD	THE BIOSYNTHESIS OF HYALURONIC ACID BY STREPTOCOCCUS,* Stoolmiller, et al., Journal of Biological Chemistry, Vol. 244, No. 2, pp. 236-246 (1969).	
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	n	"SOLUBILIZATION OF HYALURONIC ACID SYNTHETIC ACTIVITY FROM STREPTOCOCCI AND ITS ACTIVATION WITH PHOSPHOLIPIDS", Triscott et al., J. Biol. Chem., 261(13):8004-6009 (1986).	
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant,

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached,

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Complete if Known Application Number 09/469,200 Filing Date 12/21/1999 First Named Inventor Paul Weigel, et al. Group Art Unit 1653

(use as many sheets as necessary) G. Bugaisky Examiner Name of 5 Attorney Docket Number Sheet 4 35541.011

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	-4
Examiner Initials*	Cite No.1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, sental, symposium, catalog, etc.), dafe, page(s), volume-issue number(s), publisher, etc.) and/or country where publisher.	T2
	LL	"ISOLATION, STRUCTURE AND EXPRESSION OF MAMMALIAN GENES FOR HISTIDYL-IRNA SYNTHETASE," Tsui, et al., Nucleic Acids Research, Vol. 15, No. 8, pp. 3349-3367, (1987).	
	мм	"SHUTTLE VECTORS CONTAINING A MULTIPLE CLONING SITE AND A LACZA GENA FOR CONJUGAL TRANSFER OF DNA FROM ESCHERICHIA COLI TO GRAM-POSITIVE BACTERIA," Trieu-Cout, et al., Gene, Vol. 102, pp. 99-104, (1991).	
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	RR	"HYALURONATE SYNTHASE: CLONING AND SEQUENCING OF THE GENE FROM STREPTOCOCCUS SP.," Lansing, et al., J. Blochem., Vol. 289, pp. 179-184, (1993).	
	ss	*MOLECULAR CHARACTERIZATION OF HASB FROM AN OPERON REQUIRED FOR HYALURONIC ACID SYNTHESIS IN GROUP A STREPTOCOCCI," Dougherty, et al., J. Biol. Chem., Vol. 268, No. 10, pp. 7118-7124, (1993).	
	тт	*MOLECULAR CLONING, IDENTIFICATION, AND SEQUENCE OF THE HYALURONAN SYNTHASE GENE FROM GROUP A STREPTOCOCCUS PYOGENES,* DeAngells, et al., J. Biol. Chem., Vol. 268, No. 26, pp. 19181-19184, (1933).	
	υu	"MOLECULAR CHARACTERIZATION OF HASA FROM AN OPERON REQUIRED FOR HYALURONIC ACID SYNTHESIS IN GROUP A STREPTOCOCCI," Dougherty, et al., J. Biol. Chem., Vol. 269, No. 1, pp. 169-175, (1994).	
	vv	*THE STREPTOCOCCUS PYOGENES HYALURONAN SYTNHASE: SEQUENCE COMPARISON AND CONSERVATION AMONG VARIOUS GROUP A STRAINS,* DeAngelis, et al., Biochem. and Blophy. Res. Comm., Vol. 199, No. 1, pp. 1-10, (1994).	

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Application Number 09/499,200

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First Named Inventor Paul Weigel, et al.

Group Art Unit 1853

Extraction Number 35541,011

Attorney Docket Number 35541,011

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examin Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials' No. publisher, city and/or country where published. "MOLECULAR FINGERPRINTING OF PASTEURELLA MULTOCIDA ASSOCIATED WITH PROGRESSIVE w٧ ATROPHIC RHINITIS IN SWINE HERDS". Gardner et al. Database Medline on Diaolog, US Nat¹l. Library of Medicine (Bethesda, MD, USA) No. 95161494, Abstract, J. Vet. Diagn. Invest. Oct. 1994. Vol. 6, No. 4 pages "THE ELUCIDATION OF NOVEL CAPSULAR GENOTYPES OF HAEMOPHILUS INFLUENZAE TYPE B XX WITH THE POLYMERASE CHAIN REACTION. Leaves et al. J. Medical Microbiology, 1995, Vol. 43, pages 120-124, entire document. "HOMOLOGS OF THE XENOPUS DEVELOPMENTAL GENE DG42 ARE PRESENT IN ZEBRAFISH AND MOUSE AND ARE INVOLVED IN THE SYNTHESIS OF NOD-LIKE CHITIN OLIGOSACCHARIDES DURING EARLY EMBRYOGENESIS", Semino et al., Proc. Natl Acad. Sci. USA, 93:4548-4553 (1996). "ENZYMOLOGICAL CHARACTERIZATION OF THE PASTEURELLA MULTOCIDA HYALURONIC ACID 77 SYNTHASE*, DeAngelis, Biochemistry, 35 (30): 9768-9771 (1996). "CONSTRUCTION AND CHARACTERIZATION OF A POTENTIAL LIVE ORAL CARRIER-BASED VACCINE AGAINST VIBRIO CHLOLERAE", Favre et al. Infection and Immunity. September 1996. Vol. 64, No. 9 pagres 3565-3570, entire document. "MOLECULAR CLONING, EXPRESSION, AND CHARACTERIZATION OF THE AUTHENTIC hh HYALURONAN SYNTHASE FROM GROUP C STREPTOCOCCUS EQUISIMILIS", Kumari and Weigel, J. Biol. Chem., 272(51): 32539-32546 (1997). "HYALURONAN SYNTHASES", Weigel et al., J. Biol. Chem., 272 (22): 13997-14000 (1997). cc "IDENTIFICATION AND MOLECULAR CLONING OF A UNIQUE HYALURONAN SYNTHASE FROM PASTEURELLA MULTOCIDA", DeAngelis et al., J. Biol. Chem., 273(14): 8454-8458 (1998). "THE CAPSULE BIOSYNTHETIC LOCUS OF PASTEURELLA MULTOCIDA A:1. Chung, et al. FEMS Microbiol, Lett. 15 September 1998, Vol. 166, No. 2, pages 289-296, entire document.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Paul Weigel, Kshama Kumari

Atty. Dkt. No. 35541.011

and Paul DeAngelis

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Serial No.: 09/469,200

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December 21, 1999

Art Unit: 1653

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INFORMATION DISCLOSURE STATEMENT

List of Sections Forming Part of This Information Disclosure Statement

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- 1. [X] Preliminary Statements
- 2. [X] Forms PTO/SB/08A and 08B (formerly Form PTO-1449)
- 3. [X] Statement as to Information Not Found in Patents or Publications
- [] 4 Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
- Cumulative Patents or Publications 5. 1

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- 6. [X]
- Copies of Listed Information Items Acceptatement

 Concise Explanation of Non-English Language Listed Information Items

 Coarch Report

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- 8. f 1 Translation(s) of Non-English Language Documents
- 9. [] Concise Explanation of English Language Listed Information Items (Optional)
- 10. TX1 Identification of Person(s) Making this Information Disclosure Statement

Section 1. **Preliminary Statements**

Applicants submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992. 1135 O.G. 13-25, at 25.

Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)

A completed Form PTO/SB/08A and/or Form PTO/SB/08B is [X] attached hereto.

Section 3. Statement as to Information Not Found in Patents or Publications (Informati n Not Listed in Form PTO-1449)

The present invention relates to a nucleic acid segment having a coding segion segment encoding enzymatically active Streptococcup equisimilist hyaluronate synthase (seHAS), and to the use of this nucleic acid sometr in the preparation of recombinant cells which produce hyaluronate synthase distribution is hyaluronic acid product. Hyaluronate is also known as invaluronic acid or hyaluronan.

Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. ______, filed on ______ (date).

(complete the following, if applicable)

[] This application also relies, under 35 U.S.C. 120, on the earlier filing date of prior application Serial No. _____, filed on _____ (date).

The following references were submitted to, and/or cited by, the Office in the prior application(s) and therefore, are not required to be provided in this application:

Section 5. Cumulative Patents or Publications

STATEMENT

 $\underline{\hspace{1cm}}$ is cumulative of the following patents or publications listed on Form PTO-1449:

In accordance with 37 C.F.R. § 1.98(c), a copy of only ____ is being submitted with this Information Disclosure Statement.

Section 6. Copies of Listed Information Items Accompanying this Statement

RECEIVEL
Legible copies of all items listed in Form PTO-1449 (Modified) accompany,

CENTER 1600/2000 this information disclosure statement. Γ1 Exception(s) to above: Γ Items in prior application from which an earlier filing date is claimed for this application, as identified in Section 4.

> [] Cumulative patents or publications identified in Section 5.

Section 7. Concise Explanation of Non-English Language Listed Information Items

Section 7A. Concise Explanation of Non-English Language Listed Information Items - EPO Search Report

The relevance with respect to the following citations listed on Form PTO-1449:

is submitted on the basis of accompanying:

(check the appropriate item)

- Г1 EPO search report that is in the English language,
- EPO search report that is not in the English language and that is **F** 1 accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

Section 7B. Concise Explanation of Non-English Language Listed Information Items - English Language Version of EPO Search Report

Section 8. Translation(s) of Non-English Language Documents



Submitted herewith is an English translation of the following, foreign language patents, publications or information or of those potentials of those patents, publications or information consider the publications of the publica

(complete the following, if applicable)

- [] No English language translations of the foreign language parents, publications or information or parts thereof are readily available, except for those listed above.
- The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

Section 9. Concise Explanation of English Language Listed Information Items (OPTIONAL)

Section 10. Identification of Person(s) Making this INFORMATION DISCLOSURE STATEMENT

The person making this statement is the agent/attorney who signs below on the basis of the information:

- [] supplied by the inventor(s)
- [] supplied by an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c)).
- [X] in the agent/attorney's file



Respectfully submitted,

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